



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: 700 MMISS, 350 F. R. PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 737,687	12 14 2000	Darin Arthur Allen	218	1550

7590 08 04 2003

Axys Pharmaceuticals, Inc.
180 Kimball Way
South San Francisco, CA 94080

EXAMINER

WRIGHT, SONYA N

ART UNIT	PAPER NUMBER
1626	7 C

DATE MAILED: 08 04 2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/737,687

Applicant(s)

ALLEN ET AL.

Examiner

Sonya Wright

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b)

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-8 and 10-17 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 - 5) Claim(s) _____ is/are allowed.
 - 6) Claim(s) _____ is/are rejected.
 - 7) Claim(s) _____ is/are objected to.
 - 8) Claim(s) 1-8 and 10-17 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) Interview Summary (PTO-413) Paper No(s) _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Claims 1-8 and 10-17 are currently pending in the instant application.

In response to the petition decision on April 28, 2003, the following action is now taken.

Election/Restrictions

The Markush group set forth in the claims includes patentably distinct compounds (or species) within each invention. This application discloses and claims a plurality of patentably distinct compounds, far too numerous to list individually. **For this reason, restriction is required under 35 U.S.C. 121.** The following is a sample of the many species encompassed in the claim.

N-(4-carbamimidoyl-phenyl)-2-hydroxy-3-oxepane-benzamide,

class 540 subclass 544;

N-(4-carbamimidoyl-phenyl)-2-hydroxy-3-morpholino-benzamide,

class 544 subclass 169;

N-(4-carbamimidoyl-phenyl)-2-hydroxy-3-thiazinyl-benzamide,

class 544 subclass 59;

N-(4-carbamimidoyl-phenyl)-2-hydroxy-3-piperazinyl-benzamide,

class 544 subclass 400;

N-(4-carbamimidoyl-phenyl)-2-hydroxy-3-piperidinyl-benzamide,

class 546 subclass 231;

N-(4-carbamimidoyl-phenyl)-2-hydroxy-3-quinolin-2-yl-benzamide,
class 546 subclass 152;

N-(4-carbamimidoyl-phenyl)-2-hydroxy-3-quinolizin-2-yl-benzamide,
class 546 subclass 138;

N-(4-carbamimidoyl-phenyl)-2-hydroxy-3-oxazolyl-benzamide,
class 548 subclass 215+;

N-(4-carbamimidoyl-phenyl)-2-hydroxy-3-thiazolyl-benzamide,
class 548 subclass 146+;

N-(4-carbamimidoyl-phenyl)-2-hydroxy-3-imidazolyl-benzamide,
class 548 subclass 336.1;

N-(4-carbamimidoyl-phenyl)-2-hydroxy-3-pyrazolyl-benzamide,
class 548 subclass 375.1;

N-(4-carbamimidoyl-phenyl)-2-hydroxy-3-pyrrolyl-benzamide,
class 548 subclass 562;

N-(4-carbamimidoyl-phenyl)-2-hydroxy-3-pyranyl-benzamide,
class 549 subclass 426;

N-(4-carbamimidoyl-phenyl)-2-hydroxy-3-thienyl-benzamide,
class 549 subclass 77;

N-(4-carbamimidoyl-phenyl)-2-hydroxy-3-carboxy-benzamide,
class 562 subclass 405;

N-(4-carbamimidoyl-phenyl)-2-hydroxy-5-sulfoxy-benzamide
class 562 subclass 36;

N-(4-carbamimidoyl-phenyl)-2-hydroxy-benzamide
class 564 subclass 179, etc. . .

The Markush group claimed encompasses a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 U.S.C. 103.

As shown supra, the subject matter of the claims encompasses numerous classes and subclasses. The compounds encompassed by Formula I are so different that they would be separately classified and support separate patents.

An election of a single compound is required including an exact definition of each substitution on the base molecule (Formula (I)), wherein a single member at each substituent group or moiety is selected. For example, if a base molecule has a substituent group R1, wherein R1 is recited to be any one of OH, COOH, COO-C1-4 alkyl, CH₂OR₁₀, etc. . ., then applicant must select a single substituent for R1, for example OH or COOH and each subsequent variable position. In the instant case, upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim which fall into the same class and subclass as the elected compound, but may also include additional compounds which fall in related

subclasses. Examination will then proceed on the elected compound AND the entire scope of the invention encompassing the elected compound as defined by common classification. A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits. Note that the restriction requirement will not be made final until such time as applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making said compound under examination. This will be set forth by reference to specific class(es) and subclass(es) examined. Should applicant traverse on the ground that the compound are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the compound to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other.

All compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. (The provisions of 35 U.S.C. 121 apply with regard to double patenting covering divisional applications.)

Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP 608.01(p). Applicant should exercise caution in

making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

Applicant is reminded that upon cancellation of claims to a nonelected invention, the inventions must be amended in compliance with 37 C.F.R. 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

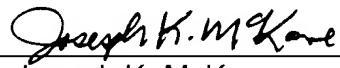
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for

draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.



Joseph K. McKane

Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

July 14, 2003